K111463

510(K) SUMMARY

FEB 17 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date of Preparation: Dec. 6, 2011

1. **Submitter's Name:** **VALEO Corporation** .
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2. **Device Name :**
   Trade Name: **Valeo VT-601 Series IR Thermometer,**
   Model no.: VT-601D , VT-601E , VT-601F
   Common Name: IR Thermometer
   Classification name thermometer, electronic, clinical

3. **DEVICE CLASS** The **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F)** has been classified as
   Regulatory Class: II
   Panel: 80
   Product Code: FLL
   Regulation Number: 21CFR 880.2910

4. **Predicate Device:** The predicate devices are the
   - BRAUN Thermoscan IRT 3020 Thermometer (K983295) marketed by BRAUN AG.&
   - EXERGEN Temporal – Scanner (K011291) marketed by EXERGEN CORP.

5. **Intended Use:** The **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F)** is infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages.

6. Device Description:

The **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D, VT-601E , VT-601F)** is hand-held, non-sterile, reusable, battery operated device that can measure human body temperature.

The **Valeo VT-601D IR Forehead/ Ear Thermometer** can measure human body temperature in 2 ways:

(1) The temporal artery over forehead.

(2) Tympanic temperature via the human ear.

The **Valeo VT-601E IR Ear Thermometer** measures human body temperature natural thermal infrared radiation emitted from the ear tympanic.

The **Valeo VT-601F IR Forehead Thermometer** measure human body temperature by the temporal artery over forehead.

Operation is based on the measuring of the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery or from the ear tympanic.

7. Comparison to 510(k) Predicate Devices & Substantial Equivalence Discussion

The **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D, VT-601E, VT-601F)** have the same intended use, principles of operation, and similar technological characteristics as predicate devices. Please find Technological Characteristics as follows

	VT-601 Series IR Thermometer	Predicate Device BRAUN Thermoscan IRT 3020 Thermometer (K983295)	Predicate Device EXERGEN Temporal - Scanner (K011291)
Regulation Number:	21CFR 80.2910	Item	21CFR 880.2910
Displayed Temperature Range	Ear: 32~43°C **Skin**: 22 ~**42.2°C** (Ear: 89.6~109.5°F **Skin:** 71.6~**107.9°F**)	34°°C~42.2°C (93.2°F~108°F)	15.5°C~42°C
Ambient Temperature Environment	1. Operating: 10°C~40 °C 2. Storage: -20°C~50°C	1. Operating: 10°C~40 °C 2. Storage: -20°C~50°C	1. Operating: 15.5°C~40°C 2. Storage: -20°C~50°C

Accuracy	**Ear:** ±0.2°C, 36~39°C ±0.3°C, the rest **Skin:** ±0.3°C, 22~40.0°C (Ear: ±0.4°F, 96.8~102.2°F ±0.5°F, the rest Skin: ±0.5°F, 71.6~104.0°F)	1. 36.0°C(96.8 °F) to 39.0°C(102.2°F): ± 0.2°C (0.4°F) 2. Outside this range: ± 0.3°C (0.5°F)	36.0°C to 39.0°C: ± 0.2°C Outside this range: ± 0.3 °C
Resolution	0.1°C / 0.1°F	0.1°C / 0.1°F	0.1°C
Display	4 digits LCD	3 and 1/2 digits LCD	3 digits LCD
Components	Main components: 1. Chip IC (μP) 2. IR Sensor 3. LCD(Liquid Crystal Display)	Main components: 1. Chip IC (μP) 2. IR Sensor 3. LCD(Liquid Crystal Display)	Main components: 1. Chip IC (μP) 2. IR Sensor 3. LCD(Liquid Crystal Display)
Power requirements	Two 1.5Vdc Alkaline Manganese battery (AAA	Two 3V CR 2032 batteries	One Alkaline 9V batteries
Power Consumption	Standby mode: 14 miliwatts Measurement mode: 8 miliwatts	1. Standby mode: 16.8 miliwatts 2. Measurement mode: 12 miliwatts	1. Standby mode: 112.68 miliwatts 2. Measurement mode: 112.68 miliwatts
Voice Function	With	No	No

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F) has the same general design with the predicate devices. It has the following similarities to the predicate devices in:

- having the same intended use
- using similar operating principle
- using similar technological characteristics

In summary, the **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F)** described in this submission is substantially equivalent to the predicate devices.

8. Non-Clinical Tests Verification

Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of **Valeo VT-601 Series IR Thermometer (Model no.: VT-601D, VT-601E, VT-601F**) is as the followings:

1) Performance Compliance Test is according to ASTM **E1965: 1998(2009)** conducted by manufacturer.
2) Electrical Safety Compliance Test is according to **IEC 60601-1** by accredited laboratory.
3) EMC Compliance Test is according to **IEC 60601-1-2** by accredited laboratory.

9. Clinical Test for Measurement Accuracy

Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device is as the followings:

A Clinical Test Report conducted according to **ASTM E 1965: 1998 (2009)** performed by the manufacturer was included as Clinical Investigation report. This report was carried out in such a way that compared the accuracy performance between **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F**) and the predicate devices according to the method recommended in **ASTM E1965** standard.

The results of the Clinical Test Report could positively support the claim of Substantial Equivalence for **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F**) against the chosen 510(k) predicate devices.

10. Conclusions:

The **Valeo VT-601 Series IR Thermometer (Model no.: VT-601D , VT-601E , VT-601F**) has the same intended use and similar technological characteristics as the BRAUN Thermoscan IRT 3020 Thermometer (K983295) marketed by BRAUN AG. & EXERGEN Temporal – Scanner (K011291) marketed by EXERGEN CORP. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics DO NOT RAISE ANY NEW QUESTIONS OF SAFETY OR EFFECTIVENESS. Thus, the **Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D , VT-601E , VT-601F**) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

VALEO Corporation
C/O Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 N. Boldt Drive
Flagstaff, Arizona 86001

FEB 17 2012

Re: K111463
Trade/Device Name: Valeo VT-601 Series IR Thermometer, Model no.: VT-601D, VT-601E, VT-601F, VALEO Corporation
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 1, 2012
Received: February 6, 2012

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: **Valeo VT-601 Series IR Thermometer,**
Model no.: **VT-601D , VT-601E , VT-601F**
VALEO Corporation

Indications for Use:

Valeo VT-601 Series IR Thermometer, (Model no.: VT-601D, VT-601E, VT-601F) is infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 2/17/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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